REMARKS/ARGUMENTS

The applicant would first like to thank the Examiner for the thorough review of the present application and for the indication that Claims 16-29 have been allowed. The applicant further requests reconsideration of the rejected claims of the application in view of the above changes to the claims and the following remarks, which are responsive to the Office Action mailed January 24, 2006.

I. Status of Claims

In the Office Action, Claims 1-43 were noted as pending in the application. As noted above, Claims 16-29 were noted as allowed. In addition, Claim 43 was noted as objected to, and Claims 1-15 and 30-42 were noted as rejected. As a result of this response, Claims 1-43 remain pending, and Claims 1, 3-5, 17, 28, 31 and 42 have been amended in order to further clarify the claimed invention. It is not believed that these amendments raise new issues and is, therefore, requested that they be substantively considered at this juncture. In particular, the amendment to Claim 1 merely changes an element of the method claim from being a passive feature to an active step of the method. In addition, the amendments to Claims 3-5, 17, 28, 31 and 42 merely clarify the intended meaning of those claims.

II. Claim Rejections

a. 35 U.S.C. §102(e) Rejection

The Official Action rejected Claims 1-15 and 30-42 under 35 U.S.C. §102(e) as anticipated by Liff et al. (U.S. Application No. 2005/0065645 A1) (hereinafter "*Liff et al.*"). (Office Action, pg. 3, para. 1). For at least the reasons set forth below, Applicant respectfully submits that Claims 1-15 and 30-42 are not anticipated by *Liff et al.* and, therefore, respectfully requests that the rejection of these claims be withdrawn.

Liff et al.

Liff et al. "is directed toward an apparatus and method for automated dispensing of packaged pharmaceuticals." (*Liff et al.*, para. 0008). In particular, the automated drug dispensing system of *Liff et al.* includes "a remote control dispenser (RCD) cabinet **20** [and] a host computer **46**" wherein a "licensed user ... operates the host computer **46** ... [to enter] a command to request dispensing of a particular packaged pharmaceutical variety **32** for a particular patient. The computer **46** transmits the request ... to a controller **42** on the RCD cabinet **20**. The controller **42** interprets the command ... and enables a dispensing actuator **68** in the appropriate column **34**" of the RCD cabinet in order to dispense the lowest package in that column. (*Id.* at para. 53).

Liff et al. further discloses a "remote pharmacist concept [that] is an extension of the remove control dispensing capabilities[.]" (*Id.* at para. 0104). According to *Liff et al.*, the following steps are performed when filling prescriptions:

1) retrieve the patient inquiry data – this defines the patient for whom the prescription is intended; the allergy, drug, and disease states of the patient; and the insurance payor(s) of the patient;
2) select the drug, signa, and other prescription-related parameters such as "refills authorized", "dispense as written", "compound code", etc.;
3) select the prescriber identification number;
4) verify information in steps 1, 2, and 3 against the prescription
5) perform drug utilization review (DUR);
6) submit claim to payor;
7) dispense and verify drug package; ...

(*Id.* at para 0104-0111). In particular, according to *Liff et al.*

> a patient presents a prescription to a technician at one of the available RCD terminals **265A-265D**. At this terminal, a pharmacy technician performs steps 1-3. The results are transmitted over the network to the R.H. workstation [i.e., the remote pharmacist (RRPH) workstation], and the pharmacist at the R.H. workstation performs steps 4-6. After the pharmacist approves the transaction, the technician at the RCD unit performs steps 7-10.

(*Id.* at para. 0119).

During steps 1-3, an "operator is presented with a menu of selections shown in **FIG. 14B.**" (*Id.* at para. 0125). The selections include "patient information **323A**, payment **323B**, drug **323C**, signa **323D**, patient medical profile **323E**, and data verification **323F**." (*Id.*).

> In the drug window **323C** ... the operator is prompted to select from a pop-down menu **505** of drugs available in the RCD units. When a drug is selected, the generic name, brand name, and NDC number of the drug available in the RCD unit automatically appears in the window ... the operator is afforded an opportunity to select a generic substitution **506**, as opposed to the brand name drug.

(*Id.* at para. 0127).

For the patient medical profile, patient medical data includes "refill information **508**, allergy information **509**, disease information **510**, and medication history **511**." (*Id.* at para. 0129). According to *Liff et al.* "[t]he allergy information is used during the drug utilization review (DUR) to determine if there is a conflict between the patient's allergy history and the prescribed pharmaceutical or any pharmaceutical in the patent [sic] profile ... the patient's disease history is tracked in a similar manner ... [and] a medication history for the patient is tracked." As noted above, the DUR is performed in step 5 by the pharmacist at the R.H. workstation after steps 1-3 have been performed (i.e., after the drug has been selected).

According to *Liff et al.*

> During a drug utilization review, the software analyzes the patient profile **336** compiled by the operator and performs a plurality of tests **337** to check for drug conflicts. The tests include: drug allergy, drug disease, drug interaction, dose check, duplicate therapy, drug food, pediatrics, geriatrics, pregnancy, lactation, disease additive, drug additive, drug induced, polypharmacy, side effects, and other standard DUR tests.

(*Id.* at para. 0131).

Independent Claim 1:

Reference is now made to independent Claim 1, which is reproduced below, as amended, for the Examiner's convenience.

1. (Currently Amended) A method, comprising:
receiving prescription information identifying a requested medical item;

creating a substitution reference list in response to said prescription information, said substitution reference list identifying at least one of said requested medical item **or** ~~and~~ an equivalent medical item; ~~and~~

automatically applying substitution rules in a database to said substitution reference list to select a medical item from said substitution reference list; and

automatically outputting dispensing information related to **the** **[[a]]** selected medical item on said substitution reference list ~~in response to the application of substitution rules is a database~~.

Applicant respectfully submits that *Liff et al.* does not teach or suggested "automatically applying substitution rules in a database to said substitution reference list to select a medical item from said substitution reference list[,]" as recited by Applicant's Claim 1.

As discussed above, according to *Liff et al.*, once an operator selects from a pop-down menu of drugs available in the RCD units, the generic and brand name drugs available appear in the window, and "the operator is afforded an opportunity to select a generic substitution **506**, as opposed to a brand name drug." In other words, an operator manually selects from between the generic substitution and the brand name drug for dispensing. This is not equivalent to "automatically applying substitution rules in a database to said substitution reference list to select a medical item from said substitution reference list."

As noted in Applicant's specification,

> [S]ubstitution rules are applied at 206 to select one of the drugs on the substitution reference list for dispensing. The substitution rules used to select one of the drugs may be based upon, for example, dispensing system configurations, medical item availability, medical item expiration date, cost, pharmacy profit potential, inventory management, work flow efficiencies (e.g., medical items' location relative to a pharmacy worker's location), and customer 32 preferences (e.g., brand name over generic names). Rules established by the FDA, State Board of Pharmacy, technicians/pharmacists 30, physicians, insurers, and customers 32 may also be taken into account. Thus, specific information incorporating knowledge of the dispensing equipment and inventory, as well as other factors and conditions, may be encoded into the substitution rules. For example, the substitution rules may cause one of the drugs on the substitution list to be picked over the others based on such factors as expiration date and inventory count at each location.

(Specification, para. 0060). Based on the foregoing, exemplary embodiments of the present invention "solve the problems inherent in other pharmacy systems by managing the allowable

medical item substitution based on inventory availability, rules established by regulatory agencies and other interested entities, and others as discussed above." (*Id.* at para. 0095).

Enabling an operator to manually select from between a generic and a brand name drug, is not equivalent to automatically applying substitution rules that are saved in a database and include rules based, for example, on dispensing system hardware configuration, medical item availability, medical item expiration date, and the like, in order to select from a substitution reference list.

For at least these reasons, Applicant respectfully submits that *Liff et al.* does not anticipate Applicant's independent Claim 1 and, therefore, requests that the rejection of independent Claim 1 under §102(e) be withdrawn.

Independent Claim 4:

Reference is now made to independent Claim 4, which is reproduced below, as amended, for the Examiner's convenience.

4. (Currently Amended) A method, comprising:
receiving prescription information;
automatically applying substitution rules from a database to said received information; and
automatically outputting dispensing information related to a ~~selected~~ medical item **selected** based on the application of said substitution rules.

Applicant respectfully asserts that *Liff et al.* does not teach or suggest "automatically outputting dispensing information related to a medical item selected based on the application of said substitution rules[,]" as recited by Applicant's Claim 4.

As noted above with respect to Claim 1, *Liff et al.* discloses enabling an operator to manually select between a generic and a brand name drug. This is not equivalent to selecting a medical item based on the application of substitution rules.

Based on the foregoing, Applicant respectfully asserts that *Liff et al.* does not teach or suggest every element of Applicant's Claim 4 and, therefore, does not anticipate that claim. As a result, Applicant respectfully requests that the rejection of independent Claim 4 under §102(e) be withdrawn.

Dependent Claims 2-3 and 5-15:

Claims 2-3 depend from independent Claim 1 and include all of the recitations of that claim plus additional recitations that further distinguish the art applied in the rejection. Thus, for at least the reasons set forth above with respect to independent Claim 1, it is submitted that dependent Claims 2-3 are further not anticipated by *Liff et al.* Claims 5-15 depend from either independent Claim 1 or independent Claim 4 and include all of the recitations of the claim from which they depend plus additional recitations that further distinguish the art applied in the rejection. Thus, for at least the reasons set forth above with respect to either independent Claim 1 or independent Claim 4, it is submitted that dependent Claims 5-15 are further not anticipated by *Liff et al.* Applicant respectfully requests, therefore, that the rejection of dependent Claims 2-3 and 5-15 under 35 U.S.C. §102(e) similarly be withdrawn.

Independent Claim 30:

Reference is now made to independent Claim 30, which is reproduced below for the Examiner's convenience.

> 30. (Original) A method for automatically filling a prescription, comprising:
> receiving prescription information identifying a requested drug;
> automatically applying substitution rules from a database to said received information;
> automatically outputting information to an automated dispensing device based on the application of said substitution rules; and
> automatically dispensing in response to said output information.

Applicant respectfully asserts that *Liff et al.* does not teach or suggest "automatically outputting information to an automated dispensing device based on the application of said substitution rules[,]" as recited by Applicant's Claim 30.

In the Office Action, the Examiner cites "the steps of review generic drug choice base [sic] on patent's [sic] medical history, rules, as shown in figures 14E, 14F, 14G, 14H, the regulations from NDC, etc." as disclosing this step of Applicant's Claim 30. Applicant respectfully disagrees.

As discussed above in the description of *Liff et al.*, the patient's medical history information is used after the drug (i.e., the generic or the brand name drug) has been selected and

during the drug utilization review (DUR) in order to check for drug conflicts. This is not equivalent to outputting information to an automated dispensing device based on the application of substitution rules.

As discussed in Applicant's specification, substitution rules "(for example, medical item equivalencies as established by the pharmacy)" may be applied to prescription information received "to create [a] substitution reference list." (Specification, para. 59). The substitution rules (e.g., "based upon, for example, dispensing system hardware configurations, medical item availability, medical item expiration, cost," etc.) may again be applied "to select one of the drugs on the substitution reference list for dispensing." (*Id.* 0060). Using a patient's medical history information to review a drug for conflicts that has already been selected is not equivalent to applying substitution rules in order to first create a substitution list and then to select a drug from the substitution list. *Liff et al.*, therefore, does not teach or suggest "automatically outputting information to an automated dispensing device *based on the application of said substitution rules*."

For at least these reasons, Applicant respectfully asserts that *Liff et al.* does not anticipate Applicant's independent Claim 30 and respectfully requests that the rejection of that claim under §102(e) be withdrawn.

Dependent Claims 31-43:

Claims 31-43 depend from independent Claim 30 and include all of the recitations of that claim plus additional recitations that further distinguish the art applied in the rejection. Thus, for at least the reasons set forth above with respect to independent Claim 30, it is submitted that dependent Claims 31-43 are further not anticipated by *Liff et al.* Applicant respectfully requests, therefore, that the rejection of dependent Claims 31-43 under 35 U.S.C. §102(e) similarly be withdrawn.

III. Conclusion

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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Laisha Richardson 3/23/06

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